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Washington, D.C. 20231, on February 14, 2002

QWINE INTELLECTUAL PROPERTY LAW GROUP, P.C.

By

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:  
RADEMACHER, Thomas William, et al.

Application No.: 09/601,971

Filed: March 29, 1999

For: IPG ANTAGONISTS FOR THE  
TREATMENT OF CONDITIONS  
INVOLVING MAST CELLS,  
BASOPHILS, AND EOSINOPHILS

Examiner: Amy M. DeCloux

Art Unit: 1644

RESPONSE TO RESTRICTION  
REQUIREMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Please reconsider the Restriction Requirement mailed December 18, 2001, in light of the remarks below.

The following documents are submitted herewith:

- 1) A transmittal sheet;
- 2) A fee transmittal sheet;
- 3) A petition for extension of time through the present date; and,
- 4) A receipt indication postcard.

RESPONSE TO RESTRICTION REQUIREMENT

Applicants elect proposed Group II, with traverse.

### **TRAVERSAL OF RESTRICTION REQUIREMENT**

Applicants traverse the restriction requirements.

#### **The Invention Does Not Lack Unity of Invention**

The Examiner alleges that Applicants' invention lacks unity of invention and imposes a restriction requirement. Applicants traverse.

According to the MPEP 1893.03(d) Unity of Invention, "an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept." "A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art." *Id.* The Examiner alleges that Applicants' invention lacks unity of invention because Claim 1 allegedly does not provide a technical feature that is distinguished over Rademacher et al., (1994) *Inositolphosphoglycan second messengers*, Brazilian J. Med. Biol. Res., 27(2):327-341 ("Rademacher").<sup>1</sup>

Claim 1 is directed to "[a] method for making a composition for the treatment of a condition mediated by the release of inositolphosphoglycans (IPGs) from mast cells, basophils or eosinophils, the method comprising providing an effective amount of an IPG antagonist in a pharmaceutically acceptable excipient, wherein the antagonist is: (a) a substance which is capable of inhibiting release of the IPGs by inhibiting the enzyme GPI-PLD; (b) a substance which is capable of specifically binding to the IPGs and inhibiting the release of histamine caused by the IPGs; or, (c) a substance which is capable of competing with IPGs released from mast cells, basophils or eosinophils but which does not cause allergic stimulation of these cell types." Unlike Applicants' invention, Rademacher does not disclose or suggest an IPG

antagonist in a pharmaceutically acceptable excipient. Rademacher also does not disclose or suggest a method for making a composition for therapeutic treatment of a condition mediated by the release of IPGs from mast cells.

In addition, Applicants' claimed invention is distinguished over Rademacher in at least the following aspects. First, Rademacher does not disclose a substance that is capable of inhibiting the release of the IPGs by inhibiting the enzyme GPI-PLD. Rademacher discusses the inhibition of histamine release and not the release of IPGs using an antibody against serum GPI-PLD. Rademacher does not even disclose that an antibody to GPI-PLD inhibits GPI-PLD.

Second, Rademacher does not disclose a substance that is capable of specifically binding to IPGs and inhibiting the release of histamine caused by the IPGs as in claim 1 of the present invention. Rademacher discusses an antibody against serum GPI-PLD. It does not disclose that this substance is capable of specifically binding to the IPGs and inhibiting the release of histamine caused by the IPGs. Third, Rademacher fails to disclose a substance that is capable of competing with IPGs released from mast cells, basophils or eosinophils and that does not cause allergic stimulation of these cell types.

Furthermore, the PCT International Preliminary Examination Report came to the opposite conclusion of the Examiner's position. Specifically, the International Preliminary Report did not find a lack of unity of invention. Furthermore, the International Preliminary Report stated that "[n]one of the documents [which includes Rademacher as D1] cited in the ISR discloses that conditions mediated by the release of IPGs from mast cells may be treated using antagonists (a) to (c) as defined in present Claim 1. Thus, the subject matter of Claims 1 to 9 is new (Article 33(2) PCT). The International Preliminary Examination Report goes on to state:

Document D1 [Rademacher] discloses that IPGs "appear to mediate the action...IgE dependent activation of rat mast cells" (see the opening paragraph in D1) and that "antibodies against serum GPI-PLD have been shown to block IgE-stimulated

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Footnote continued from previous page

<sup>1</sup> Although the Action indicated that the reference was found in Nature, the reference was not found in Nature. Applicants assume the above reference cited in the response is correct because it was found in the international preliminary examination report and a submitted IDS.

histamine release in rat mast cells (15) which is IPG dependent" (see the first paragraph on page 334 of D1). Document D1 supports these statements by referring to an abstract (see reference 15) which reports that antibodies against serum GPI-PLD can be used to block IgE stimulated histamine release in vitro in rat mast cells which have been sensitized with anti-TNP and triggered with TNP-OVA. Thus, document D1 appears to provide some results linking IPG's, GPI-PLD and allergy. In view, however, of the following deficiencies in document D1, it does not seem, to be obvious to use the GPI-PLD inhibitor of this document, i.e., anti-GPI-PLD antibody, to treat conditions mediated by the release of IPG's from mast cells; a) the teaching of document D1 seems wholly directed towards elucidating cellular receptor mechanisms and there seems to be no suggestion or pointer in document D1 towards development of therapeutic treatments of any type and; b) the mechanism of IPG release described in document D1 is not completely clear, in particular it was not known whether serum or mast cell GPI-PLD was involved in IPG release (see page 334 of D1). Hence the teaching of document D1 is insufficiently definitive and seems to fall short of showing that the skilled person would have had a reasonable expectation of success when using antagonists (a) to (c) as defined in present Claim 1 for the treatment of conditions mediated by the release of IPGs from mast cells, basophils or eosinophils. Consequently, the subject matter of Claims 1 to 9 appears to be inventive (Article 33(2) PCT).

International Preliminary Examination Report, Section V, Nos: 5-6.

Furthermore, the International Preliminary Examination Report states that D1 supports that Applicants' invention has unity of invention. Specifically, the Report states that "[D]ocument D1 [Rademacher] appears to provide some results linking IPG's, GPI-PLD, and allergy." International Preliminary Examination Report, Section V, No: 5. Based on the arguments above, along with the findings in the International Preliminary Examination Report, the restriction requirement should be withdrawn because the application contains a single general inventive concept under PCT Rule 13.1 and 37 CFR 1.499 and has technical features that distinguish it over Rademacher.

Even assuming, arguendo, that Applicants' application lacked unity of invention, which it does not for at least the reasons above, Applicants traverse the restriction requirement and respectfully request that the Examiner rejoins the groups as follows:

II-III, VI-IX, Parts of I, X-XIV

Claims 1-9, 15-20

Becomes Group I

V, Part of I	Claims 11-14	Becomes Group II
Part of X-XIV	Claims 21-23	Becomes Group III
IV	Claim 10	Becomes Group IV

As noted in more detail below, this grouping conforms to current PTO restriction practice and is not believed to present an undue burden for examination. If the above restriction is adopted by the Examiner, Applicants elect resulting group I.

The Restriction Requirement Does Not Conform to PTO Restriction Practice

As enumerated in the Restriction Requirement, each of groups I-III comprises the same claims 1, 2, and 15. Similarly, groups VI-IX each comprise the same claims, 16, 17, and 20; groups X-XIV comprise the same claims, i.e., 16, and 18-23; groups I, and VI-XIV comprise the same claims 16 and 20; and groups I and VI-IX comprise the same claim 17. On its face, the restriction requirement is flatly improper.

The Restriction requirement is improper because it does not exhaustively restrict the invention or provide for the sum of the parts equaling the whole claim.

Applicants traverse the restriction of the claims because the restriction requirement does not conform to the articulated PTO policy of requiring restriction only when the sum of the parts (i.e., the restricted groups) can be made equal to the whole (the original claim before restriction), or if the invention can be restricted exhaustively.

Applicants submit that the restriction of independent claim 1 into separate groups (Groups I, II and III) impairs the scope of the claim as originally written. Claim 1 is drawn to methods for making compositions for the treatment of a condition mediated by inositolphosphoglycans (IPGs) from mast cells, basophils or eosinophils using an IPG antagonist and lists three types of antagonists which are as follows: "(a) a substance which is capable of inhibiting release of the IPGs by inhibiting the enzyme GPI-PLD; (b) a substance which is capable of specifically binding to the IPGs and inhibiting the release of histamine caused by the IPGs; or (c) a substance which is capable of competing with IPGs released from mast cells, basophils or eosinophils but which does not cause allergic stimulation of these cell types."

Restriction of independent claim 1 into 3 separate groups (Groups I, II and III), presumably based upon type of antagonist for inhibiting release of an IPG from a mast cell, a basophil or an eosinophil, and the like, does not provide for the sum of the parts to equal the

whole, which is the current PTO policy regarding restriction. In addition, the restrictions of independent claim 16 into 10 separate groups (Groups I, VI-XIV), which is drawn to methods for inhibiting release of IPG using an IPG antagonist, and the restriction of independent claim 21 into 5 separate groups (Groups X-XIV), which is drawn to methods for treating a condition mediated by the release of IPGs with an effective amount of an IPG antagonist, are presumably based upon the type of IPG antagonist, whether the method is done in vitro or in vivo, or the like, also does not provide for the sum of the parts to equal the whole. Since the restrictions were not a species election for the purpose of examination, Applicants submit that the restrictions were completely improper, and should, therefore, be withdrawn.

The restriction requirement does not conform to the court's prohibition against rejection of a particular claim on the basis that it represents independent and distinct inventions.

In addition, Applicants traverse the restriction to the claims, because the restriction requirement does not conform to the 35 U.S.C. § 121, as expressly articulated by the Courts.

As a preliminary matter, alleging that a particular claim represents multiple patentably distinct inventions is a *de facto* rejection to the patentability of the claim, because the claim cannot issue as drafted. As the C.C.P.A. noted (emphasis added):

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

*In Re Weber, Soder and Boksay*, 198 USPQ 328, 331 (C.C.P.A. 1978). See also *In Re Haas*, 179 USPQ 623,624, 625 (*In Re Haas I*) (C.C.P.A. 1973) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*) (C.C.P.A. 1978).

It has long been held that an Examiner simply may not reject a particular claim on the basis that it represents independent and distinct inventions (which is the very definition of unity of invention). See *In Re Weber, Soder and Boksay, supra*. The courts have definitively ruled that the statute authorizing restriction practice, i.e., 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. See *In Re Weber, Soder and Boksay, In Re Haas I and In Re Haas II*. In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. For example, *In Re Weber* (198 USPQ 328) sets forth the following (see 331-332):

It is apparent that § 121 provides the commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be 'independent and distinct.' It does not, however, provide a basis for an examiner, acting under the authority of the commissioner to reject a particular claim on the same basis.

*In Re Haas* (198 USPQ 335) interprets this as a *per se* holding, in the very next case by the court:

In *In Re Weber*...decided of even date, this court holds that § 121 does not provide a basis for rejection of a claim. To the extent that § 121 was employed as a basis for rejection, that rejection is, on the authority of *Weber*, reversed.

As the Court has also noted:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim—no matter how broad, which means no matter how many independently patentable inventions may fall within it.

*In Re Weber, Soder and Boksay* 198 USPQ at 338.

Instead of improperly imposing a restriction requirement on a single claim, the Examiner may limit initial examination to a reasonable number of species encompassed by the claim. See 37 C.F.R. § 1.146. This practice strikes an appropriate balance between the concerns of the Patent Office regarding administrative considerations and unduly burdensome

examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. § 112 are complied with. *See MPEP* at 803.02. *See also, In Re Wolfrum*, 179 USPQ 620 (C.C.P.A. 1973) and *In re Kuehl* 177 USPQ 250 (C.C.P.A. 1973). Unlike the restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications which are simply incapable of capturing the intended scope of the invention.

Applicants submit that the 14 Groups, as proposed by the Office Action, have been improperly restricted. Single claims, e.g., 1, 2, and 15-23, have been broken apart by the Examiner and divided into the Examiner's multiple groups, e.g., Groups I-III, and VI-XIV, thereby preventing Applicants from ever pursuing the original form of the claims.

**This is an express example of a procedure which is absolutely and unequivocally forbidden by the Courts, i.e., the restriction is a rejection of claims 1, 16, 21 and additionally of each of claims 2, 15, 17-20, and 22-23 made under the supposed authority of the divisional statute, 35 USC § 121. As the Courts have definitively ruled, the divisional statute provides no such authority.**

Applicants also submit the groups X (claims 16, 18-23); XI (claims 16, 18-23), XII (claims 16, 18-23), XIII (claims 16, 18-23), and XIV (claims 16, 18-23) as stated in the Office Action have been improperly restricted. The claims listed in Groups X, XI, XII, XIII and XIV include the same claims 16, 18, 19, 20, 21, 22 and 23.

Similarly, Applicants also submit that Group VI (claims 16, 17, 20), VII (claims 16, 17, 20), VIII (claims 16, 17, 20) and IX (claims 16, 17, 20) as stated in the Office Action has been improperly restricted. The claims listed in Groups VI, VII, VIII, and IX include the same claims 16, 17, and 20. In addition, groups I (claims 1, 2, and 15), II (claims 1, 2, and 15), and III (claims 1, 2, and 15) are improperly restricted; along with groups I, and VI-XIV which comprise the same claims 16 and 20; and groups I and VI-IX comprise the same claim 17.

Applicants respectfully submit, for the reasons discussed above, that the restriction of claims 1, 2, and 15-23 into multiple groups is improper. In light of the case law cited above, Applicants submit that the Office is simply forbidden from restricting a single claim (i.e., 1, 2, 15, 16, 17, 18, 19, 20, 21, 22, 23) into multiple groups, because 1) such a restriction is

necessarily a rejection of the claim (i.e., there is no application where an applicant is permitted to pursue the claim as drafted); and 2) the court has explicitly held that § 121 does not provide a basis for such a rejection (and the court has, quite bluntly held that this is a per se holding).

Because the restriction is improper, Applicants respectfully request that the groups be rejoined as described above. In particular, Applicants request that the claims of Group II-III, VI-IX, and parts of I, X-XIV be considered as a single group (resulting Group I), the claims of Groups V and part of I be considered a single group (resulting Group II), and the claims of parts of groups X-XIV be considered as a single group (resulting Group III). In accordance with the proposed rejoinder and renumbering of the groups, Group IV remains Group IV. The suggested claim grouping is, thus:

Claims 1-9, 15-20	Becomes Group I
Claims 11-14	Becomes Group II
Claims 21-23	Becomes Group III
Claim 10	Becomes Group IV.

Finally, Applicants note that the courts have explicitly held that improper restriction of a single claim is a decision under the jurisdiction of the Board of Appeals, and the Federal Courts. This is in contrast to simple administrative decisions regarding ordinary restriction requirements, which are not generally subject to Appellate review. *See In Re Haas I, supra*. Because restriction of a single claim into multiple groups is a rejection and a refusal to examine the claim as drafted, as articulated in *Haas I*, the Board of Appeals and the courts have jurisdiction over the decision. Accordingly, Applicants expressly reserve the right to appeal any decision that may be made regarding the present Restriction Requirement to the Patent Office Board of Appeals and to the Federal Circuit, in this or any future related application.

### **CONCLUSION**

#### **The Restriction Requirement Must be Withdrawn.**

As set forth above, the restriction requirement in the present case must be withdrawn. There is no lack of unity of invention. This is supported by the arguments expressed above and the International Preliminary Examination Report. Even if there was a lack of unity

of invention, which there is not, there is no statutory authority for imposing a restriction requirement on any particular claim as done in the Action. The courts have expressly held that the type of restriction requirement made by the Examiner is an improper rejection subject to Appellate review. Simply put, the Courts have expressly held that an Examiner may not use 35 U.S.C. § 121 as a basis for rejection of a particular claim.

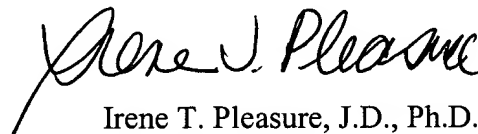
Finally, a 14-way restriction in the present case clearly violates the firm dictates of the Patent Office practice regarding restriction practice as set forth in the MPEP. It should be apparent that imposing a 14-way restriction requirement on the pending claims would be manifestly unfair to the Applicants, violating the balance between the administrative interests of the Office and the Applicants' constitutional and statutory rights as an inventor.

To conform to the requirements of the restriction order, Applicants have elected with traverse, that claims 1b, 2, 3, and 15 (Examiner's Group II) be examined in the present invention. However, Applicants traverse the restriction requirement in the strongest terms.

**In the event that requirement is maintained, Applicants hereby request an interview with the Examiner, Supervisory Examiner Paula Hutzell and group Director John Doll before issuance of any additional action by the Examiner.**

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 510-337-7971.

Respectfully submitted,



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